REMARKS

Claims 1-3, 6-15 and 28-33 are pending, wherein claim 7 was amended. No claims were added or cancelled by this amendment. Reconsideration and allowance for the above-identified application are now respectfully requested.

As discussed during the Examiner Interview held on December 2, 2008, the claimed implant devices provide an advantage over previous methods and devices used to insert bone growth promoting granules into a tooth extraction site or other bone defect. The claimed implant devices include a dry covering that initially encapsulates a bone growth promoting material prior to use and which becomes gelatinous and adhesive upon contact with moisture (*e.g.*, blood) in order to retain the bone growth promoting material within a tooth extraction site or other bone defect during use. This was concretely illustrated by a live demonstration presented during the Examiner Interview in which the inventor drew his own blood, placed it into a tooth extraction site of a dental model, and then inserted an inventive implant device into the tooth extraction site. The outer covering of the implant device, which was made from oxidized cellulose, immediately become gelatinous and adhesive upon contacting the blood and was highly effective in retaining the bone growth promoting granules within the tooth extraction site. Afterwards, the undersigned attorney witnessed the fact that the gelatinous mass adhered strongly to the socket and could only be removed with much effort. By comparison, bone growth promoting granules inserted within a tooth extraction site and moistened with blood in the absence of the covering were easily dislodged during the demonstration when exposed to water.

In addition, the initially dry covering helped with initial placement of the bone growth promoting granules into the tooth extraction site as compared to inserting granules from a bottle or syringe, which have a tendency to spill and scatter.

Moreover, the ability of the initially dry covering to quickly become a gelatinous and adhesive mass permits the bone growth promoting granules to be reshaped into the specific shape of a tooth extraction site or other bone defect. This provides an important advantage as compared to implant devices that include covers made from hydrophobic polymers or other materials that do not immediately form a gelatinous mass upon contact with blood. In the case of an extracted molar, which leaves behind three holes where the three roots were previously connected to the bone, the claimed implant devices, upon being wetted with blood, can be molded like a putty and pushed into the three holes. In contrast, implant devices that include slowly degrading covers made from polylactic acid, polyglycolide, and other non-gelatinizable

materials cannot be molded as a putty but remain in their original shape in order to carry out their intended purpose.

Accordingly, as was further explained during the Examiner Interview, the claimed implant devices are designed to serve a different purpose than the devices disclosed in Tormala and Silverberg, which do not have a covering that becomes gelatinous and adhesive when exposed to moisture, such as water or blood. Instead, the outer shells of Tormala and Silverberg are made of hydrophobic polymer materials such as polyglycolic acid or polylactic acid, are designed to persist in their original shape for weeks, and are only slowly resorbed by the body over time during bone ingrowth. Thus, an important distinction between the dry covering of the claimed implant devices and the devices shown in Tormala and Silverberg is *not* the time in which the materials are resorbed by the body but rather the time in which the initial structure of the materials breaks down when exposed to moisture. The dry coverings of the inventive implant devices quickly form a gelatinous and adhesive mass when exposed to moisture even if the gelatinous mass is only resorbed slowly by the body over a period of days or weeks. That is quite different than the outer shells of Tormala and Silverberg, which are designed to persist in their original shapes during bone ingrowth.

According to Tormala, "the surgical products and devices (implants) which are manufactured of resorbable polymers have an advantage that they are digested during a *certain period of time* without needing a separate removal operation, like implants which are manufactured of biostable materials (*e.g.*, of metals) often used." Col. 3, lines 35-41 (emphasis added). "[T]he resorption times of the above polymers can vary in different cases from about *one week up to several years*." Col. 4, lines 29-31 (emphasis added). Most importantly, Tormala teaches that

> When the bone tissue grows *inside of the supporting structure* from the orifice and when connective tissue grows *from sides and from above the supporting structure* through its porosity *inside the supporting structure* it is fixed rapidly with the bone and soft tissues at the same time when rapid ossification proceeds from the base of the supporting structure between the bone graft powder particles and also inside of them when it is a case of porous bone graft particles.

Col. 2, lines 60-68 (emphasis added). This teaching makes it abundantly clear that the Tormala device is designed to remain structurally intact over at least the period of time it takes for bone to begin growing through the bottom "orifice" of the "supporting structure" and "inside the

supporting structure" (*i.e.*, within the interior of outer shell or casing 1). Such bone in-growth within the Tormala device takes weeks to occur, as indicated by Example 2. In Example 2, the outer chute was still intact after 6 weeks. Col. 8, lines 26-34. Such growth of bone through the orifice and inside the supporting structure would not be possible if the outer shell were designed to quickly form a gelatinous and adhesive mass. Thus, the slow breakdown and resorption of the *structure* (*i.e.*, shape) of the Tormala device is critical for the device to perform its intended function of building up and augmenting bone in a person who has lost all their teeth along the alveolar ridge of the jaw bone, as is clearly shown in Figure 3 of Tormala.

Moreover, Figure 3 shows an elongated implant device inserted through a passageway under the gums. As taught in Tormala,

> The surgeon can apply the bone graft implant in an operation for example in such way that he makes on the surface of alveolar ridge below the gingival tissue an elongated subperiosteal tunnel, into which the resorbable chute (1) is pushed in such a way that the convex surface of the chute is directed to the gingival tissue and the end surfaces (p) of the sides of the chute are placed against the alveolar ridge. This situation is described schematically in FIG. 3 in the case a bone graft operation which is done to the right side of the mandible.

Col. 5, line 61 – col. 6, line 3.

The Tormala device could not be inserted through the incision, under the stretched gums, and placed lengthwise over the alveolar ridge if the outer shell were to become gelatinous and adhesive when exposed to moisture (*i.e.*, blood resulting from making the incision through the gums). It is difficult, if not impossible, to insert a wet sticky noodle into a tight orifice. Accordingly, there was no reason to modify Tormala in order to replace the rigid outer chute shown in Figures 2a-2f, which is constructed using one of the hydrophobic polymers listed in Table 1 of Tormala, with an outer covering that becomes gelatinous and adhesive upon contact with water or blood. To do so would render the Tormala device unsuitable for its intended purpose of being insertable through a narrow incision under the gums and placed lengthwise over the alveolar ridge, as shown in Figure 3 of Tormala. According to MPEP 2143.01, a proposed modification cannot render Tormala unsatisfactory for its intended purpose of providing a rigid and elongated chute that can be pushed through a narrow incision under the gums and positioned lengthwise over the alveolar ridge.

A similar argument applies to Silverberg, which teaches that the outer mesh covering of the Silverberg degrades slowly over time as the void space in the bone is replaced with bone tissue. "Progressive absorption of the mesh along with the simultaneous ingrowth of connective tissue serves to *maintain a desired contour during healing*." Col. 3, lines 52-54 (emphasis added). The outer mesh covering is made from hydrophobic materials such as polyglycolic acid, which do not form a gelatinous and adhesive mass upon contact with water or blood. Moreover, Silverberg likewise discloses a procedure in which the elongated device is inserted into a narrow incision through the gums and over the alveolar ridge. *See* Figures 3-5. Like Tormala, it would be contrary to the teachings and purposes of Silverberg to replace the outer polyglycolic acid or similar resorbable hydrophobic polymer covering with a dry cover that becomes gelatinous and adhesive upon contact with water. The Silverberg device could not be pushed through the incision and positioned lengthwise over the alveolar ridge if the outer shell became gelatinous and adhesive when exposed to moisture (*i.e.*, blood resulting from making the incision through the gums). Accordingly, there was no reason to modify Silverberg in order to replace the outer mesh covering, which is constructed using polyglycolic acid or other non-gelatinizable hydrophobic materials, with an outer covering that becomes gelatinous and adhesive upon contact with water or blood. To do so would render the Silverberg device unsatisfactory for its intended purpose of being insertable within a narrow incision under the gums and placed lengthwise over the alveolar ridge, as shown in Figures 3-5 of Silverberg. *See* MPEP 2143.01. Moreover, Silverberg teaches the importance of "maintain[ing] a desired contour during healing", thus leading away from a material such as oxidized cellulose that becomes gelatinous and structurally breaks down upon being contacted with blood found in a bone defect. In view of this, even if one were to combine Tormala and Silverberg, their combined teachings would only suggest a device for use in augmenting the alveolar ridge. As such, any hypothetical device made by combining Tormala and Silverberg must be insertable through a narrow incision, pushed under the stretched gums, and placed over the alveolar ridge as shown in the drawings of Tormala and Silverberg. Therefore, one of skill in the art would have had no reason to combine Tormala and Silverberg with Kenyon to obtain the claimed implant devices.

Kenyon has nothing to do with filling bone defects with bone growth promoting granules but merely discloses a gelatinizable gauze material. During the Examiner Interview the Examiner stated that it would be "easy" to substitute the outer shell coverings of Tormala and Silverberg with the gelatinizable gauze material of Kenyon. Many inventions are *easy* once

known but "easiness" is not a legally recognized test for determining obviousness and is not a criterion in any known rule of claim examination. In order to establish that a claim is *prima facie* obvious over a combination of references, there must be a valid reason why one of skill in the art would have combined the references to obtain the claimed invention. The problem with combining Kenyon with Tormala and Silverberg is that such a substitution would render the elongated, generally rigid, and non-adhesive devices of Tormala and Silverberg unsatisfactory for their intended purpose of being insertable through a narrow incision under the gums and placed lengthwise over the alveolar ridge.

The covering materials used in Tormala and Silverberg are hydrophobic polymers such as PLA and polyglycolide, not gelatinizable materials that become adhesive upon contact with moisture. If one were to substitute the hydrophobic polymer coverings of Tormala and Silverberg with a material such as oxidized cellulose that becomes gelatinous and adhesive upon contact with water, the hypothetical Tormala-Silverberg device would no longer be suitable for its intended purpose of being insertable through a narrow incision in the gums and placed over the alveolar ridge. *See* MPEP 2143.01. Moreover, the gelatinizable gauze of Kenyon would not maintain the supporting structure of the Tormala device in its desired shape to allow bone growth through the orifice and into the interior of the chute (*See* Tormala, col. 2, lines 60-68). Nor would the gelatinizable gauze of Kenyon maintain the desired mesh structure of the Silverberg device in order to permit bone to growth ***through*** the mesh structure over time and also so that the implant device is able to "maintain a desired contour during healing" (*see* Silverberg, col. 3, lines 52-54). Accordingly, there was no teaching, suggestion, motivation or other reason why one of skill in the art would have modified the implant devices of either Tormala and Silverberg to include the gelatinizable gauze material of Kenyon.

In view of the foregoing, claim 1 and the claims that depend therefrom are patentable over the art of record.

Claim 7 is further patentable over the applied art because it claims a device having a "pillow-like configuration" (*e.g.*, a short pellet as demonstrated during the Examiner Interview), which is neither taught nor suggested in any of the cited references. The Tormala et al. and Silverberg devices are, by necessity, elongate structures having a length that is several times their width so as to enable them to extend lengthwise over the alveolar ridge. *See* Tormala, Figures 2-3; Silverberg, Figures 1, 2 and 4. A device having a non-elongate, pillow-like configuration is not suitable for augmenting the alveolar ridge. There was no teaching, suggestion, motivation or

other reason at the time of the invention to modify Tormala et al. and Silverberg to obtain an implant device having the pillow-like configuration of claim 7.

Claims 9 and 10 further claim an adhesive mixed within the bone growth promoting material. None of the cited references disclose or suggest a device having a dry covering that is water-gelatinizable and which consists essentially of oxidized cellulose in combination with an adhesive mixed with the bone growth promoting material.

Claim 14 recites specific method steps that are neither taught nor suggested in the applied art. For example, claim 14 requires that, upon placing the device is adjacent to bone tissue, the covering becomes gelatinous upon contact with water in order to maintain the bone growth promoting material adjacent to bone tissue. In contrast, neither Tormala et al. nor Silverberg disclose or suggest a method in which the implant device becomes gelatinous upon contact with water in order to maintain the bone growth promoting material adjacent to bone tissue. Instead, a resorbable hydrophobic polymer such as polyglycolide merely maintains a shell around the bone growth material until bone has grown into the shell. Thereafter, the resorbable shell material is slowly resorbed over time when replaced with bone. Moreover, as the wound dressing in Kenyon is not used in connection with any bone growth material, Kenyon fails to disclose or suggest a method in which the wound dressing maintains a bone growth promoting material adjacent to bone tissue. Accordingly, the combined teachings of Tormala et al., Silverberg and Kenyon fail to disclose every element recited in claim 14 such that claim 14 is not *prima facie* obvious over these references.

Claim 28 is similar to claim 1 but further claims a thickener dispersed among the bone growth promoting material that forms a *viscous gel* or *firm putty* upon contact with water. Tormala et al. does not disclose any such device. Instead, Tormala et al. discloses an embodiment in which resorbable polymer fibers are *melted together* while forming the implant device in order to bind the bone growth particles together. "Such a material can be manufactured for example by mixing ceramic powder with resorbable polymer and by *melting or sintering the mixture to a solid sample*". Col. 5, lines 3-6 (emphasis added). Tormala et al. does not disclose or suggest any embodiments that include "a thickener dispersed among the bone growth promoting material that forms a viscous gel or firm putty upon contact with water" as recited in claim 28. Accordingly, claim 28 is clearly patentable over Tormala et al. The Office Action fails to identify any other reference that allegedly contains such teachings. Similar to Tormala et al., Levy discloses the use of proteins that are *heat melted* together to bind calcium-containing

particles together. Col. 3., lines 19-26; col. 4, lines 13-25. Like Tormala et al., Levy neither teaches nor suggests a device constructed so that a thickener (*e.g.*, which is an initially dry, chopped or powdered material) forms a viscous gel or firm putty upon contact with water. Accordingly, claim 28 is not *prima facie* obvious over any combination of references identified in the Office Action.

Claim 30 further specifies that "the thickener comprises at least one of gelatinizable gauze, oxidized cellulose, oxidized regenerated cellulose, ground catgut, or powdered catgut". In contrast, Tormala et al. merely discloses the use of unnamed resorbable polymer fibers that can be melted or sintered to form a solid ceramic structure. *See* col. 3, lines 1-2; col. 4, lines 65-69; col. 5, lines 1-6. Levy discloses fibrin or collagen that is heat melted together to bind particles but not the materials recited in claim 30.

Claim 31 further specifies that "the thickener comprises a biocompatible gelatinous collagen material", which is neither taught nor suggested in Tormala et al. or any other reference as a thickener that can be used to bind the particles together upon contact with water (*e.g.*, Levy discloses heat melting of collagen).

The Office Action argues that Applicant attacks each reference individually. This is not so. All the rejections set forth in the Office Action start by citing Tormala as the primary reference. As such, any modifications required to obtain the claimed invention must be consistent with and not contrary to the teachings of Tormala. Moreover, they must not render Tormala unsuitable for its intended purpose. *See* MPEP 2143.01. In addition, rejections based on improper hindsight are forbidden. Tormala discloses that certain features are critical, such as the enlarged bottom orifice and the ability of the device to persist long enough in its initial shape to permit in-growth of bone through the enlarged orifice and into the interior of the device. It is improper to allege that it would be obvious to modify Tormala to exclude the critical and necessary features of the disclosed device. Thus, Applicant does not attack Tormala, but rather seeks to uphold the integrity of what Tormala actually teaches, which is something quite different than Applicant's invention. Moreover, Applicant's arguments that one of skill in the art would not have had any reason to modify Tormala to incorporate features of Silverberg and Kenyon in a manner that would render the Tormala device unsatisfactory for its intended purpose is clearly not arguing each reference individually. Instead, it is the application of the rules articulated by the Supreme Court in *Graham v. John Deere* and *KSR v. Teleflex*, wherein the

Court requires there to be some teaching, suggestion, motivation or other reason why one of skill in the art would have modified the primary reference to obtain the claimed invention.

Both *Graham* and *KSR* emphasize that one alleging that a claim is unpatentable may not engage in improper hindsight, using the claims as a guide to reconstruct the invention from unrelated and/or contradictory teachings found in multiple references. The fact that Kenyon is unrelated to filling bone defects with bone material is evidence that one of skill in the art would *not* have combined Kenyon with Tormala and Silverberg, particularly since the material used in Kenyon is designed to immediately become sticky when contacted with blood. If one were to make the covers used in Tormala and Silverberg using the materials of Kenyon, the resulting device would no longer be capable of being inserted through a narrow incision, pushed through the gums, and placed over the alveolar ridge, which is a critical aspect of both Tormala and Silverberg. Combining Kenyon with Tormala and Silverberg does violence to the respective teachings contained therein. Applicant merely wishes to uphold the clear teachings in Tormala and Silverberg that lend away from the Kenyon material because such a substitution would render the devices of Tormala and Silverberg unsuitable for their intended purpose. Accordingly, any argument that one of skill in the art would have modified Tormala and Silverberg to include a cover made from the material of Kenyon would be based on pure hindsight, using the present claims as a guide to pick and choose only so much of the references as would support the rejection, while ignoring contrary teachings that lead away from the claimed invention. *See Gore v. Garlock.*

Finally, the Office Action states that the Application does not identify the precise chemistry of oxidized cellulose that renders it gelatinizable and adhesive upon contact with water. In response, Applicant points out that the use of oxidized cellulose for wound dressings that become adhesive when contacted with blood was well-known at the time of the invention. Therefore, Applicant may rely on the general state of the art at the time the Application was filed since one of skill in the art, after reading and understanding the claimed invention, could readily select an oxidized cellulose material to yield a device having the claimed features. The claimed invention is the *combination* of oxidized cellulose with a bone growth promoting material in the specific configuration claimed, not the selection of a particular type of oxidized cellulose.

In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account N o. 23-3178**.

Dated this 16th day of January 2009.

Respectfully submitted,

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